Remarks

Reconsideration and allowance of the subject application are respectfully requested.

Claims 1-8 are pending in this application, with Claims 1 and 8 being independent. In this Amendment, Claims 1-2 and 6-8 have been amended. All amendments are being made for reasons of clarity with respect to the specification and drawings, and not for reasons relating to the statutory requirements for patentability.

Rejections under 35 U.S.C. 102

Claims 1-8 stand rejected under 35 U.S.C. 102 (e) as being anticipated by Fodgaard (U.S. Patent No. 5,817,007). Applicant respectfully traverses this rejection for the reasons set forth below.

Fodgaard discloses a method of determining the concentration of a blood constituent that involves extracting a stream of blood, at a flow rate of 50-1,000 ml/min, and directing this whole blood stream through a flow-through measuring cuvette having an optically transparent surface part, and then irradiating the optically transparent surface part of the flow-through measuring cuvette with multi-wavelength near infrared (NIR) light. This is followed by detecting, and quantifying the concentration of the blood constituent. (See, for example, Col. 1, line 66 to Col. 2, line 22.)

The method of Fodgaard differs from the presently claimed method for at least the reason that it involves irradiating a stream of blood within a *flow-through* cuvette (see item 24 in Figures 1, 4 and 14; or item 90 in Figures 5 and 6). In Col. 8, lines 41-43, it is stated that the cuvette "constitutes a central or essential component of the whole blood analyzing apparatus." This method does not detect constituents of blood located within a blood bag, or within tubing in fluid communication with the blood bag, as set forth in the present claims. Furthermore, there is no teaching or suggestion

within Fodgaard that a blood bag, or tubing in fluid communication with a blood bag, can be used in place of a flow-through cuvette.

The methods claimed in Claims 1-8 are therefore novel in view of Fodgaard, and Applicant respectfully requests that the rejection under 35 U.S.C. 102(e) be withdrawn. Furthermore, Applicant submits that the features of at least Claim 1 are also not suggested in Fodgaard, and that one of skill in the art would not have been directed to the methods presently claimed upon reading Fodgaard as there is no suggestion that the flow-through cuvette may be replaced with the blood bag or associated tubing. Therefore, it is submitted that Claim 1, and dependent Claims 2-8, are also not obvious in view of Fodgaard.

Claims 1-4 and 6-8 stand rejected under 35 U.S.C. 102(b) as being anticipated by Bonner (U.S. Patent No. 4,522,494). Applicant respectfully traverses this rejection for the reasons set forth below.

Bonner discloses a method for determining the platelet concentration in plasma contained in a transfusion bag by producing a periodic laminar flow within the blood bag to assist in orienting the platelets and allowing the platelets to become randomized, followed by irradiating the sample with a HeNe laser and measuring, at a selected scattering angle, the scattered light intensity of the plasma. The concentration of platelets in the plasma is then determined using a computer program. (See, for example, Col. 2, lines 6-29.)

The method of Bonner differs from the method of the present claims for at least the reason that it involves determining a scattered light intensity of *non-aggregated platelets* contained in a transfusion bag, rather than an absorbance of an *analyte* in a blood bag. The term "analyte" is defined within the present specification on page 13, line 13, as a chemical component, and may include hemoglobin, bilirubin, biliverdin, Intralipid™, methylene blue, cross-linked hemoglobin, and other analytes. There is no

teaching or suggestion in Bonner that the disclosed method may be used to determine the concentration of an analyte in a blood bag as claimed in the present invention. Furthermore, an absorbance value of a plasma sample cannot be used to determine the concentration of platelets in a plasma sample according to the method of Bonner, as the method of Bonner uses a computer program that requires a scattered light intensity value. Additionally, the method of Bonner involves periodic agitation of the blood within the blood bag during a measurement cycle in order to ensure that the concentration of non-aggregated platelets is determined. (See Col. 2, lines 30-32.) Such a step is not required for the determination of an analyte in blood bag according to the presently claimed invention.

Applicant submits that Claims 1-4 and 6-8 are, therefore, novel over Bonner, and respectfully requests that the rejection of Claims 1-4 and 6-8 under 35 U.S.C. 102(b) be withdrawn. Furthermore, Applicant submits that the features of Claim 1 are not suggested in Bonner, and that one of skill in the art would not have been directed to the presently claimed methods upon reading of Bonner, as there is no suggestion that the absorbance of an analyte may be determined. Therefore, it is also submitted that Claim 1, and the claims that depend from Claim 1, are not obvious in view of Bonner.

Rejections under 35 U.S.C. 103

Claim 5 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Bonner (U.S. Patent No. 4,522,494) in view of Weythman (U.S. Patent No. 4,128,830). Applicant respectfully traverses this rejection for the reason set forth below.

As argued above, the method of Bonner differs from the method of the present claims. For example, the method of Bonner involves determining platelet concentration using scattered light intensity of a sample contained in a transfusion bag, rather than the concentration of an analyte using absorbance. There is no suggestion in Bonner that the concentration of an analyte may be determined by measuring

absorbance. This deficiency of Bonner is not remedied by combination with Weythman, which discloses compensating a signal for light sensors. There is no disclosure or suggestion in Weythman of determining the concentration of an analyte in a blood bag by measuring absorption.

Applicant further submits that Claim 5 depends from Claim 1, and therefore incorporates the features of Claim 1, none of which are disclosed or suggested by Bonner and Weythman, either alone or in combination. The claims of this application are, therefore, inventive over the combination of Bonner and Weythman, and Applicant respectfully requests that this rejection of Claim 5 under 35 U.S.C. 103(a) be withdrawn.

In view of the amendments and remarks set forth above, Applicant submits that this application is in condition for allowance, and respectfully requests prompt issuance of a notice thereof.

Applicant's undersigned attorney may be reached in our Washington, D.C. office by telephone at (202) 625-3500. All correspondence should continue to be directed to our address given below.

Respectfully submitted,

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